REMARKS

Initially, Applicant would like to point out that the Examiner erroneously made this Office Action final. According to the Manual of Patent Examining Procedure, § 706.07(a), "second or any subsequent actions on the merits shall be final, except where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p)." Here, the Examiner introduced new grounds of rejection. Yet, Applicant neither amended any of the claims in responding to the two earlier office actions nor submitted any information disclosure statement after the mailing date of the first office action. Thus, Applicant requests that the finality of this Office Action be withdrawn.

Applicant has replaced the title of this application and corrected typographical errors in the Specification. Applicant has also corrected a minor deficiency in claim 1. No new matter has been introduced by the above amendments. Claims 1-21 are currently pending. Reconsideration of the application, as amended, is requested in view of the remarks below.

Rejection under 35 U.S.C. § 112, first paragraph

Claims 1-17 are rejected as failing to comply with the enablement requirement. See the Office Action, page 3, lines 8-9. To support his rejection, the Examiner relies on relevant factors set forth in *In re Wands* 8 USPQ2d 1400 (CAFC, 1988), including: nature of the invention, breadth of the claims, state of the art, guidance of the specification, predictability of the art, and the working examples. See the Office action, page 3, lines 12-15. Applicant respectfully traverses below. Claim 1, an independent claim, will be discussed first.

Nature of the invention

The Examiner comments that "the nature of the invention is extremely complex in that it encompasses a number of tumors or metastasis conditions and inhibiting the growth of the tumors, which involves the treating and preventing the tumors." See the Office Action, page 3, lines 17-19.

Claim 1 is drawn to a photodynamic method treatment. More specifically, it covers a method of inhibiting the growth of tumor cells in a tumor site in a subject by administering to the tumor site an effective amount of an oligoaniline and subsequently exposing the tumor site to irradiation. Upon irradiation, the oligoaniline converts surrounding molecular oxygen to highly reactive oxygen radicals, such as superoxide radicals. The radicals in turn attack and damage the tumor cells, thereby inhibiting their growth. See the Specification, page 3, lines 21-23. Thus, contrary to the Examiner's belief, the nature of the invention is not "extremely complex." Indeed, the method of claim 1 is rather simple and can be practiced by a person skilled in the art.

Breadth of the claims

The Examiner then contends that "the complex nature ... is exacerbated by the breadth of the claims [since] the claim[s encompass] prevention as well as treatment of tumors that may or may not have been addressed in the specification ...." See the Office Action, page 3, lines 19-22. Applicant disagrees.

The method of claim 1 does not prevent tumor formation as asserted by the Examiner. As discussed above, claim 1 is limited to inhibiting tumor growth in an already-identified tumor site in a subject. In other words, the scope of claim 1 is not as broad as alleged by the Examiner.

State of the art

The Examiner asserts that "[t]he state of the art does not recognize the administration of compositions to inhibit the growth of all types of tumors using a single compound." See the Office Action, page 3, line 22 to page 4, line 1.

As discussed above, claim 1 has a limited scope and does not cover a method of inhibiting growth of all types of tumor cells using a single compound. Rather, it covers a method of inhibiting the growth of any tumor cells in a tumor site in a subject. The state of the art is such that a person skilled in this field would know any tumor cells, regardless of their types, in an already-identified tumor site can be treated by the method of claim 1. After all, the photodynamic treatment of claim 1 can be used to inhibit the growth of any cells. Thus, to practice the method of claim 1, an oligoaniline compound must be administered to a tumor site first and then only the tumor site is irradiated so as to minimize the damages to non-tumor cells.

Guidance of the specification

The Examiner contends that "the guidance given by the specification on how to inhibit growth of different types of tumors is absent." See the Office Action, page 4, lines 1-2.

First, the Examiner asserts that "the instant specification describes *in vitro* inhibition of murine sarcoma cells, the specification does not provide any guidance as to how to extrapolate the same or other tumors *in vivo*, in situ or to other animals, birds or human," See the Office Action, page 4, lines 3-5. Applicant disagrees. Contrary to the Examiner's assertion, the Specification does describe an *in vivo* for inhibiting murine sarcoma cells in mice. See Example 4. In this assay, mice were divided into groups (1) and (2). Mice in both groups were inoculated with murine sarcoma cells, which were allowed to proliferate to reach a size with a diameter about 1 cm. Mice in group (1), but not mice in group (2), were then treated with an oligoaniline recited in claim 1. Subsequently, mice in both groups were exposed to irradiation at the tumor site. The results show that the average tumor weight of the mice in group (1) was about 40% (a 60% reduction) of the average tumor weight of the mice in group (2). With the guidance of this example, a skilled person in the art would be able to use the method of claim 1 to inhibit the growth of tumor cells in a tumor site in other animals, including humans.

The Examiner also asserts that "[t]he specification also fails to teach if the treatment is effective in completely inhibiting the tumor cell growth." See the Office Action, page 4, lines 5-9. Claim 1 does not require complete inhibiting the tumor cell growth. It merely recites "inhibiting," not "complete inhibiting." Applicant therefore submits that claim 1 is supported by the Specification even if the Specification does not teach completely inhibiting tumor cell growth. Indeed, partial inhibition of tumor growth is still useful. Example 4 of the Specification also discloses that this method resulted in a 60% tumor reduction in mice, which is significant in tumor treatments.

Finally, the Examiner asserts that "whether the administration of the instant composition is effective in inhibiting the growth of a tumor cell at any stage of the tumor, i.e., early or late stage." See the Office Action, page 4, lines 9-11. As discussed above, the photodynamic treatment of claim 1 can be used to inhibit the growth of any cells, including tumor cells in a tumor site. An ordinary person skilled in the art would know that tumors in an already-identified tumor site, regardless at their early or late stage, can all be treated by the method of claim 1.

For the reasons set forth above, Applicant submits that the Specification has provided a reasonable amount of guidance to support a method of inhibiting the growth of tumor cells in a tumor site of a subject as required by claim 1.

Working examples/undue experimentation

Finally, the Examiner asserts that "the practitioner would turn to trial and error experimentation to make/use the instant compositions for inhibiting the growth of different types of tumor cells, at different stages of growth cycle, without guidance from the specification or the prior art. Therefore, undue experimentation becomes the burden of the practitioner." See the Office Action, page 4, lines 14-17. Applicant disagrees.

Applicant would like to point out that "[a] considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed (emphases added)." In re Wands, 8 USPQ2d 1400, 1404 (CAFC 1988), citing In re Jackson, 217 USPQ 804, 807 (CCPA 1969).

Photodynamic therapy was well known at the time the invention was made. See the Background section of the Specification. It is a mere routine procedure within the skill of an ordinary person in this field. The patentability of claim 1 resides, at least in part, in the use of certain oligoaniline compounds recited in this claim, not in the photodynamic approach. Even if the photodynamic therapy is not a routine procedure, the Specification has provided a reasonable amount of guidance including three actual working examples, Examples 2-4.

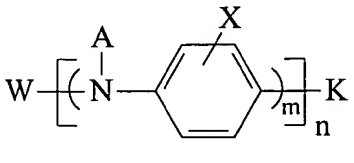
For the reasons set forth above, claim 1 is enabled by the Specification. So are claims 2-17, all of which depend from claim 1.

It is submitted that claims 1-17, not subjected to other grounds of rejection, are now in condition for allowance.

Rejection under 35 U.S.C. § 103(a)

Claims 18-21 are rejected as being obvious over Dickey et al., U.S. Patent No. 2,492,972 ("Dickey") or Grell et al., GB 2,090,834 ("Grell"). See the Office Action, page 2, lines 7-8.

Claim 18, an independent claim, will be discussed first. It covers a pharmaceutical composition containing an oligoaniline of formula (I):

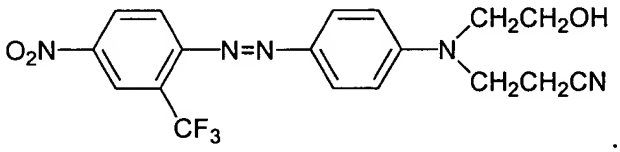


(I),

in which m, n, A, W, X, and K are defined in claim 18. More specifically, K is H or an arylamino group, at the 4-position of the aniline ring, containing at least one phenylene group bonded to the amino moiety of the arylamino group. X can be -NH-E-D and E is -R-, -R-Ar-, -Ar-R-, or -Ar-, in which R is C_{1-30} alkyl and Ar is aryl.

The Examiner contends that "[the] formula [at column 3, lines 25-30] of Dickey meets the description requirement of instant aniline compounds, particularly with respect to the variables W, K, and A, as claimed." See the Office Action, page 2, lines 10-13. The Examiner also contends that "Dickey fails to teach pharmaceutical compositions ... However, Dickey teaches [an] aqueous suspension, which reads on a pharmaceutically acceptable carrier." See the Office Action, page 2, lines 12-13. The Examiner then proceeds to conclude that Dickey renders claim 18 obvious. Applicant disagrees.

Dickey teaches using azo compounds to dye or color textile materials. Specifically, Dickey discloses, at column 3, lines 25-30, an azo compound of the following formula:

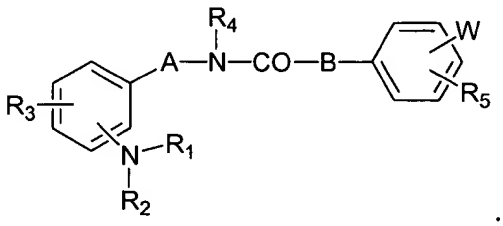


In this compound, an aniline was substituted at the 4-position with an azo group which contains a nitrogen-nitrogen double bond. This azo group is substantially different from the groups assigned to K, which is also a substituent at the 4-position of the aniline ring (see formula (I) above). Specifically, K at most is an arylamino group which does not contain a nitrogen-nitrogen double bond. Thus, the azo compounds disclosed in Dickey are substantially different from the compounds of formula (I). Note that even if K is H, m is 1, and n is 2, the compound of formula (I) is a dianiline, which still does not contain a nitrogen-nitrogen double bond. Thus,

Dickey does not disclose or even suggest any oligoaniline compound of formula (I), let alone the pharmaceutical composition for inhibiting tumor cell growth recited in claim 18.

The Examiner further asserts that "NR_1R_2 [in formula (I) of Grell] reads on instant NAW ... [and] variable R_3 [in formula (I) of Grell] ... meets the requirement of the instant variable K." See the Office Action, page 2, lines 20-21. Applicant disagrees.

Grell discloses a compound of the following formula for treating disorders of intermediary metabolism:



In this formula, assuming NR_1R_2 corresponds to NAW of formula (I) and R_3 corresponds to K of formula (I), as so assumed by the Examiner, then A-N(R_4)-CO-B-phenyl corresponds to X of formula I. When A is a single bond, A-N(R_4)-CO-B-phenyl is an amide group, i.e., N(R_4)-CO-B-phenyl, which is closest to the group assigned to X. By contrast, X at most is -NH-E-D, in which E is -R-, -R-Ar-, -Ar-R-, or -Ar-, where R is C_{1-30} alkyl and Ar is aryl. Thus, X at most is an amino group bonded to an alkyl or aryl group, not an amide group in which an amino group is bonded to a carbonyl group as required by N(R_4)-CO-B-phenyl.

Even assuming NR_1R_2 corresponds to NAW, R_3 corresponds to X, and A-N(R_4)-CO-B-phenyl corresponds to K, the compounds disclosed in Grell are still substantially different from the compounds of formula (I). Specifically, A-N(R_4)-CO-B-phenyl is closest to the groups assigned to K when A is a single bond. However, as mentioned above, K at most is an arylamino group in which the amino group is bonded to a phenyl, not an amide group in which an amino group is bonded to a carbonyl group.

Thus, in view of the above remarks, Grell clearly does not disclose or even suggest any compound of formula (I), much less the pharmaceutical composition recited in claim 18.

For the reasons set forth above, claim 18 is not rendered obvious by Dickey or Grell. Neither are claims 19-21, all of which depend from claim 18.

CONCLUSION

Applicant submits that the grounds for rejection asserted by the Examiner have been overcome, and that claims 1-21, as pending, define subject matter that is enabled and nonobvious. On this basis, it is submitted that all claims are now in condition for allowance, an action of which is requested.

Please apply any other charges to deposit account 06-1050.

Respectfully submitted,

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